

of treating or ameliorating inflammation in an individual by administering orally an effective amount of (-)-hydroxycitric acid. The Examiner reasons that the Applicant was not in possession of the claimed invention because “[s]uch a method requires treatment of unspecified disease and no evidence indicates that treatable disease was known to the applicant.” 10/11/2006 Office Action at page 2, ¶2. The Examiner concludes that “[i]n the absence of understanding of the disease to be treated, the artisan would not have accepted that applicant was in possession of the claimed invention.” 10/11/2006 Office Action at page 2, ¶2. The Applicant traverses the Examiner’s rejection for the following reasons.

The fundamental factual inquiry for compliance with the written description requirement of 35 U.S.C. § 112, first paragraph is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). While a question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently (see, e.g., *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997)), there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). Claims 1-6 of the instant matter are essentially original claims as filed and they should therefore benefit from a strong presumption that an adequate written description of the claimed invention is present in the specification as filed.

The Applicant submits that claims 1-6 do not fail for lack of written description pursuant to 35 U.S.C. § 112, first paragraph because the claims are directed to a physiological process which was well-recognized by the artisan at the time the instant application was filed. As noted above, claims 1-6 of the instant application are directed to “treating or ameliorating inflammation in an individual...”. “Inflammation is the first response of the immune system to infection or irritation and may be referred to as the innate cascade. Inflammation is characterized by the following quintet: redness (rubor), heat (calor), swelling (tumor), pain (dolor) and dysfunction of the organs involved (*functio laesa*). The first four characteristics have been known since ancient

times and are attributed to Celsus; *functio laesa* was added to the definition of inflammation by Rudolf Virchow in 1858.” See [en.wikipedia.org/wiki/Inflammation](http://en.wikipedia.org/wiki/Inflammation). The PDR Medical Dictionary defines “inflammation” in part as a “fundamental process consisting of a dynamic complex of cytologic and chemical reactions....” [emphasis added]. In contrast, disease has generally been defined in three ways: (1) an interruption, cessation, or disorder of body functions, systems, or organs; (2) a morbid entity characterized usually by at least two of these criteria: recognized etiologic agent(s), identifiable group of signs and symptoms, or consistent anatomical alterations; and (3) literally, dis-ease, the opposite of ease, when something is wrong with a bodily function (Dirckx, *Stedman's Concise Medical Dictionary for the Health Professions*, 3rd Edition 1997. Williams and Wilkins). The claimed method is therefore directed to treating or ameliorating a physiological response to tissue injury or insult, not a specific disease. As such, the Applicant submits that the Examiner reasoning and conclusion that “[i]n the absence of understanding of the disease to be treated, the artisan would not have accepted that applicant was in possession of the claimed invention” is erroneous because the Examiner is not employing the accepted medical definition of “inflammation” as a “response” or “process.”

The Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an Applicant's disclosure a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d at 263, 191 USPQ at 97. See MPEP §2163.04. The Applicant submits that the Examiner has not met his burden under 35 U.S.C. § 112, first paragraph to challenge the adequacy of the written description of claims 1-6 because claims 1-6 should have a strong presumption of an adequate written description in the application as filed and the Examiner's reasoning does not appear to be founded on the long accepted medical definition of “inflammation” as a “response” or “process.” Accordingly, the Applicant respectfully requests that the Examiner's rejection of claims 1-6 pursuant to 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

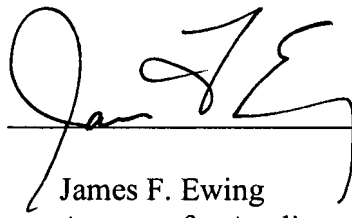
The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-3431. Should no proper payment be enclosed herewith, as by the credit card payment instructions being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-3431. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-3431.

Respectfully submitted,

Date April 11, 2007

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